

EU Quality Management System Certificate ES23/00000120

The management system of

Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

C/ Pelaya 9, Polígono Industrial Rio de Janeiro, 28110 Algete (Madrid). Spain.

SRN: ES-MF-000017998

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2, 3, 4, and 5 of this certificate

This certificate is valid from 06 February 2023 until 06 February 2028 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 06 August 2027

Issue 1. Certified since 06 February 2023



Authorised by

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Sociedad Española de Electromedicina y Calidad S.A. (SEDECAL)

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIb devices:

Active non-implantable imaging devices utilising ionizing radiation (MDA0201, MDS1009);

X-Ray Generator SHF:

SHF-1010, SHF-1015, SHF-1020, SHF-1025, SHF-1030, SHF-1035,
SHF-1610, SHF-1615, SHF-1620, SHF-1625, SHF-1630, SHF-1635,
SHF-210, SHF-215, SHF-220, SHF-225, SHF-230, SHF-235,
SHF-310, SHF-315, SHF-320, SHF-325, SHF-330, SHF-335,
SHF-410, SHF-415, SHF-420, SHF-425, SHF-430, SHF-435,
SHF-510, SHF-515, SHF-520, SHF-525, SHF-530, SHF-535,
SHF-610, SHF-615, SHF-620, SHF-625, SHF-630, SHF-635, SHF-835,
SHF-1610 PSU, SHF-1615 PSU,
SHF-210 PSU, SHF-215 PSU,
SHF-310 PSU, SHF-315 PSU,
SHF-410 PSU, SHF-415 PSU, SHF-510 PSU, SHF-515 PSU
SHF-1610-C, SHF-1615-C,
SHF-210-C, SHF-215-C,
SHF-310-C, SHF-315-C,
SHF-410-C, SHF-415-C,
SHF-510-C, SHF-515-C
SHF-0510-M, SHF-0530-M, SHF-1010-M, SHF-1030-M,
SHF-0510-MPSTA, SHF-1010-MPSTA
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

X-Ray Generator SHFR:

SHFR100, SHFR200, SHFR300, SHFR400, SHFR500, SHFR600, SHFR800
(EMDN: Z11039011; Basic UDI-DI: 843604600GENERATORBD)

Mobile X-Ray Generator:

SM-IV
SM-V
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILEGENCG)

Battery Mobile X-Ray Unit PHOENIX:

PHOENIX
AeroDR TX m01
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Battery Mobile X-Ray Unit EASY MOVING:

SM-20HF-Batt, SM-32HF-Batt, SM-40HF-Batt, SM-50HF-Batt
SM-20HF-B-D-C, SM-32HF-B-D-C, SM-40HF-B-D-C, SM-50HF-B-D-C
SM-20HF-B-D-TEZ, SM-32HF-B-D-TEZ, SM-40HF-B-D-TEZ, SM-50HF-B-D-TEZ
SM-20HF-B-D-FDX, SM-32HF-B-D-FDX, SM-40HF-B-D-FDX, SM-50HF-B-D-FDX
SM-20HF-B-D-FDXW, SM-32HF-B-D-FDXW, SM-40HF-B-D-FDXW,
SM-50HF-B-D-FDXW
SM-20HF-B-D-KM (AeroDR X30), SM-32HF-B-D-KM (AeroDR X30),
SM-40HF-B-D-KM (AeroDR X30), SM-50HF-B-D-KM (AeroDR X30)
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)



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Capacitor Mobile X-Ray Unit MOBIXRAY:

SMR-16, SMR-20, SMR-32
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Portable X-Ray Unit SPL:

SPL-HF-2.0, SPL-HF-4.0, SPL-HF-8.0
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Portable X-Ray Unit DRAGON X:

SPSL-HF-4.0, SPSL-HF-8.0,
SPSL-HF-4.0-APR, SPSL-HF-8.0-APR,
SPSLW4, SPSLW8, SPSL4HC, SPSL8HC
(EMDN: Z11039016; Basic UDI-DI: 843604600MOBILECM)

Radiographic System SEDECAL X:

SEDECAL X BRS, Composed of:
Radiographic Positioner: SEDECAL X BRS
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

SEDECAL X URS, Composed of:

Radiographic Positioner: SEDECAL X URS
Control Box: SEDECAL X URS
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

SEDECAL X PLUS LP PLUS, Composed of:

Radiographic Positioner: SEDECAL X PLUS LP PLUS
Control Box: SEDECAL X PLUS LP PLUS
(EMDN: Z11039005; Basic UDI-DI: 843604600UNIVERSALUF)

Radiographic System MILLENNIUM:

MILLENNIUM, Composed of:
Tube Stand MILLENNIUM: MILL-FMTS
Tube Stand MILLENNIUM: MILL-FMTS-TS
Tube Stand AD MILLENNIUM: MILL-FMTSAD
Fixed Height Table MILLENNIUM: MILL-FWFTT-B
Elevating Table MILLENNIUM: MILL-EL-B
Wall Stand MILLENNIUM: MILL-WBS
Wall Stand MILLENNIUM: MILL-WBS-TS
Tomography MILLENNIUM: MILL-TOMO
Power Supply: BRAKE BOX
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)



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MILLENNIUM PLUS AT, Composed of:

Tube Stand MILLENNIUM PLUS AT: MILL-FMTSAT-PLUS
Elevating Table MILLENNIUM PLUS AT: MILL-ELAT-PLUS
Wall Stand MILLENNIUM PLUS AT: MILL-WBSAT-PLUS
Wall Stand Manual Tilting: TWBS-TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

MILLENNIUM PLUS TPC, Composed of:

Tube Stand MILLENNIUM PLUS TPC: MILL-FMTSTPC-PLUS
Elevating Table MILLENNIUM PLUS TPC: MILL-ELTPC-PLUS
Wall Stand MILLENNIUM PLUS TPC: MILL-WBSTPC-PLUS
Wall Stand Manual Tilting: TWBS-TILT
Tomography MILLENNIUM PLUS: MILL-TOMO-PLUS
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

Radiographic System PROTEUS XR/f:

PROTEUS XR/f ET, Composed of:

Tube Stand MULTIRAD: MULT-FMTS
Elevating Table NET 4000: NET 4000-ST
Wall Stand MILLENNIUM: MILL-WBS
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

PROTEUS XR/f ST, Composed of:

Tube Stand MULTIRAD: MULT-FMTS
Table MULTIRAD: MULT-FWFTTD
Wall Stand MILLENNIUM: MILL-WBS
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

Radiographic System MULTIRAD:

MULTIRAD (Proteus), Composed of:

Tube Stand MULTIRAD: MULT-FMTS
Table MULTIRAD: MULT-FWFTT
Wall Stand MULTIRAD: MULT-WBS
Power Supply: BRAKE BOX
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

MULTIRAD NET, Composed of:

Tube Stand MULTIRAD: MULT-FMTS
Elevating Table NET 4000: NET 4000-ST
Wall Stand MULTIRAD: MULT-WBS
Wall Stand MILLENNIUM: MILL-WBS
Power Supply: BRAKE BOX
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)



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Radiographic System NOVA:

NOVA FA, Composed of:
Elevating Table NET 4000: NET 4000-AU
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-AU
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

NOVA AT, Composed of:
Ceiling Suspension NOVA: NOVA AT
Elevating Table NET 4000: NET 4000-AT
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-AT
Wall Stand Manual Tilting: TWBS-TILT
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

NOVA ST, Composed of:
Ceiling Suspension NOVA: NOVA ST
Elevating Table NET 4000: NET 4000-ST
Moving Elevating Table: FLEXI-DT
Wall Stand NBS 2100: NBS 2100-ST
Wall Stand Manual Tilting: TWBS-TILT
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

Radiographic System CHALLENGE X:

CHALLENGEX AP, Composed of:
Ceiling Suspension CHALLENGE X: CHAP
Elevating Table NET400: NET400AP
Elevating Table NET500: NET500AP
Wall Stand CHALLENGE X: CHWSAP
X-Ray Generator Console: STH
(EMDN: Z11039005; Basic UDI-DI: 843604600SYSTEMPS)

X-Ray Generator Console:

X Ray Generator Console: CTSC
(EMDN: Z11039006; Basic UDI-DI: 843604600CONSOLEM9)

Conditions for & limitation to the validity of the certificate:

For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available "on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on - ES/MAD/c300002079 - S2A 1.4

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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